

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Charles R. Ashby Jr.	Examiner:	Rae, Charlesworth E.
Serial No.:	10/776,108	Group Art Unit:	1614
Confirmation No.:	2666	Docket:	BSA 04-09
Filed:	February 10, 2004		
For:	The Use of Vitamin B6 To Mitigate Visual Field Defects Associated With The Use Of GABAergic Drugs In Mammals		

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. 1.132

Sir:

I, Dr. Charles R. Ashby, Jr., declare as follows:

1. I am the inventor of the subject matter claimed in the above-identified application.
2. I am currently a Professor of Pharmaceutical Sciences in the College of Pharmacy at St. John's University located in Jamaica, Queens, New York.

3. I have taught at St. John's for 12 years and have lectured to students about all classes of therapeutic agents. I have served as a consultant for 12 different pharmaceutical companies and have served on the editorial board of 3 peer reviewed journals. In addition, I have served as a reviewer of manuscripts for 15 different journals.

4. I have reviewed the Office Action dated August 20, 2007, as well as the references cited therein.

5. There are a number of distinct and well-documented differences between butyrates, as described in Evans et al., and gamma vinyl GABA (GVG).

6. Current pharmacological knowledge indicates that butyrates, such as magnesium butyrate, are precursors for GABA but have no effect on GABA levels in the brain as they do not cross the blood-brain barrier. GVG, on the other hand, is not a GABA precursor. Rather, GVG is an irreversible inhibitor of GABA-transaminase, and significantly increases brain GABA levels via inhibition of GABA metabolism.

7. Butyrates, as disclosed in Evans et al., are not interchangeable with GVG. A person of ordinary skill in the art would not consider the two to be equivalents, suitable substitutes for one another, or interchangeable in methods of treatment.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. Further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Dated: 10/27/07

Charles R. Ashby, Jr., Ph.D.
Charles R. Ashby, Jr.